Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KEVIN WEADOCK,
DAVID J. LENTZ, and
RICHARD J. ZDRAHALA

Appeal No. 2002-1007
Reissue Application No. 09/391,762

HEARD: April 3, 2003

Before WILLIAM F. SMITH, NASE, and MILLS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision in an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 18, all the claims pending in this reissue application.

Claims 1 and 13 are representative of the subject matter on appeal and read as follows:

1. An implantable member for use in repair or replacement with a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, said pores filled with a fluid which solidifies and is crosslinked to form a solid precipitate of a [sic] insoluble biocompatible, biodegradable material of natural origin said material being insoluble at a pH of about 7.4.

13. An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils; and a biodegradable composition of natural origin contained within said pores, said biodegradable composition forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.

The references relied upon by the examiner are:

Okita	4,193,138	Mar. 18, 1980
Hoffman, Jr. et al. (Hoffman '977)[1]	5,197,977	Mar. 30, 1993
Alonso	5,037,377	Aug. 6, 1991
Jernberg	5,290,271	Mar. 1, 1994

Tran et al. (Tran), "Plasma Modification and Collagen Binding to PTFE Grafts," Journal of Colloid and Interfacial Science, Vol. 132, no. 2, pp. 373-381 (October 15, 1989)

A reference relied upon by the merits panel is:

Kaehler et al. (Kaehler), Precoating Substrate and Surface Configuration Determine Adherence and Spreading of Seeded Endothelial Cells on Polytetrafluoroethylene Grafts," Journal of Vascular Surgery, Vol. 9, no. 4, pp. 535-541, April 1989

Claims 13 through 18 are rejected under 35 U.S.C. § 251 on the basis of the "reissue recapture doctrine." Claim 13 stands rejected under 35 U.S.C. § 102(e) or alternatively under 35 U.S.C. § 103(a) on the basis of Jernberg. Claims 1 through 8 and 11 through 18 stand rejected under 35 U.S.C. § 102(b) or in the alternative under 35 U.S.C. § 103(a) on the basis of Tran. Claims 1 through 10, 13 through 16 and 18 stand rejected under 35 U.S.C. § 103(a) with the examiner relying upon Hoffman '977 and Okita as evidence of obviousness. Claims 1 through 8, 11, 13 through 16, and 18

[1] The examiner relied upon Hoffman '977 in the final rejection as well as the Examiner's Answer. However, the examiner lists U.S. Patent No. 4,842,575, also to Hoffman, Jr. et al., as being relied upon at page three of the Answer. We consider the latter listing to be an inadvertent error on the part of the examiner.

also stand rejected under 35 U.S.C. § 103(a) with the examiner relying upon Alonso and Okita as evidence of obviousness.

For reasons which follow, we do not reach the merits of the examiner's rejections in view of the new grounds of rejection under the provisions of 37 CFR § 1.196(b) set forth infra.

Background

1. Procedural Background.

This reissue application seeks reissue of U.S. Patent No. 5,665,114 ('114 patent). The '114 patent issued on September 9, 1997, containing claims 1 through 12. The patented claims have not been amended during prosecution of this reissue application. However, claims 13 through 18 have been added since patentees believe that the '114 patent is "partly inoperative or invalid by reason of our claiming less than we had a right to claim in the original patent. Specifically, we believe that the original patent is partly inoperative or invalid for including limitations in the claims which were not required by the prior art." Reissue declaration, page 2. Patentees further explain the reasons for this reissue application, stating:

> Claim 13 of the reissue application corresponds generally with claim 1 of the '114 patent. Claim 13, however, differs from claim 1 in at least one respect including, for example:
>
> The limitation 'said material being insoluble at a pH of about 7.4. The pH range claimed in claim 1 is operative only for certain specific materials set forth in examples in the specification. The requirement that the material be insoluble at a specific pH of 7.4 was not required by the prior art.

> This and other limitations in the claims resulted from the apparent failure of ourselves and our patent counsel to fully appreciate the limiting nature of the cited limitations, as well as a failure to fully appreciate the full scope of the invention as taught by the specification. During prosecution of the application, we did not fully realize or appreciate the effect of these limitations on the scope of coverage provided by the claims.
>
> We have always felt that a significant aspect of the present invention is that the prosthesis of the present invention includes fluid material in the pores defined between the nodes and fibrils of the expanded polytetrafluoroethylene substrate and that the fluid solidifies in its cross-link to form a solid precipitate of insoluble biocompatible biodegradable material with that material being insolubilized in place. We believe that the absence of the requirement that the material being insoluble at a specific pH of 7.4 enables the full scope of the invention to be appreciated.
>
> Furthermore, we believe that all errors being corrected in the present reissue application arose without deceptive intention on our part.

Reissue declaration, pages 2-3.

The examiner has invoked the reissue recapture doctrine in regard to newly added claims 13-18. Ball Corp. v. United States, 729 F.2d 1429, 1436, 221USPQ 289, 295 (Fed. Cir. 1984)("The recapture rule bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope than those claims that were canceled from the original application." (footnote omitted)). The examiner explains

> Present claims 13-18 are improper for a reissue application because they attempt to recapture subject matter surrendered in order to overcome a prior art rejection. Specifically, during the pendency of the patented file 08/289,790, the language 'filled with fluid which solidifies and is crosslinked to form' and 'said material being insoluble at a pH of about 7.4' was added in order to overcome a prior art rejection. Therefore, it is improper to attempt to recapture this subject matter via claims 13-18 in the present reissue application.

Examiner's Answer, page 4, last paragraph.

The '114 patent is based upon Application No. 08/289,790 ('790 application). Prosecution in the '790 application progressed to the point that an appeal to this Board was filed. Subsequently an Appeal Brief was filed ('790 application, Paper No. 13), an Examiner's Answer was entered ('790 application, Paper No. 15), and a Reply Brief was filed ('790 application, Paper No. 16). Claims 1 through 12 as pending in the '790 application at the time of the Examiner's Answer were all rejected on the basis of prior art. '790 application, Examiner's Answer, pages 4-6. Subsequent to the Reply Brief but before the '790 application was forwarded to the Board for a decision, an interview was held between counsel and the examiner which resulted in an Examiner's Amendment that amended the pending claims, withdrawal of all prior art rejections, and issuance of the patent. '790 application, Interview Summary (Paper No. 17); Examiner's Amendment (Paper No. 18). Claim 1 of the '790 application prior to the Examiner's Amendment read as follows:

> 1. An implantable member for use in repair or replacement with a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, said pores containing a solid insoluble biocompatible, biodegradable material of natural origin.

Claim 1 was amended to read as reproduced above as a result of the Examiner's Amendment and the '114 patent issued.

2. Technical Background.

The invention described in the '114 patent concerns implantable devices made from expanded polytetrafluoroethylene (e-PTFE) having improved ability to bind with

body tissues, higher resistance to suture leakage and enhanced blood tightness. '114 patent, column 1, lines 6-9. The inventors of the '114 patent explain:

> e-PTFE porous tubers made by stretching and sintering have been used as tubular prostheses for artificial blood vessels for a number of years. These polymeric tubes have certain advantages over conventional textile prostheses, but also have disadvantages of their own. The e-PTFE tube has a microporous structure consisting of small nodes interconnected with many thin fibrila. The diameter of the fibrils, which depend on the processing conditions, can be controlled to a large degree and the resulting flexible structure has greater versatility in many aspects than conventional textile grafts. For example, e-PTFE grafts can be used in both large diameter, i.e., 6 mm or greater artificial blood vessels, as well as in diameters of 5 mm or less.

'114 patent, column 1, lines 18-30. The present invention is stated to be an improvement over previous e-PTFE substrates used as implantable substrate prostheses. As explained:

> Thus far, e-PTFE substrates still suffer from endothelial cell adherence problems. The resent invention is an attempt to address this problem, along with the problem of suture hold bleeding, by introducing into the porous walls of the 3-PTFE prosthesis a solid natural material such as collagen, gelatin or derivatives of these materials. In addition to the above advantages, material such as collagen also serves to denucleate 3-PTFE. Denuclearization removes air pockets and therefore reduces the thrombogenicity of the e-PTFE thesis assimilation into the surrounding tissue, enhance the healing process as well as provide a more blood-tight prosthetic implant.

'114 patent, paragraph bridging columns 1 and 2. The invention of the '114 patent is summarized as follows:

> The prostheses of the present invention include expanded PTFE substrates having pores present in the substrate wall structure wherein said pores contain a solid biocompatible material of natural origin. These biocompatible, biodegradable materials are selected from generally extracellular matrix proteins as will be further described hereinbelow. Extracellular matrix proteins are known to be involved in cell-to-cell and

> cell-to-matrix adhesion mechanisms. The pores of the present invention are present in the expanded PTFE structure as the interstices of the node/fibril configuration. As previously mentioned, the pore size is dependent on the processing and stretching parameters used in preparation of the tubular substrate. For purposes of this invention, the term 'pores' will be used interchangeable with other terms such as interstices, voids and channels.
>
> The present invention also concerns a method of making the biomaterial-containing PTFE prostheses. The method involves contacting and/or filling the voids of the e-PTFE substrate with a fluid containing a soluble biocompatible material which is capable of solidifying and preferably cross-linking to form an insoluble material, and preferably cross-linking of the biocompatible material is accomplished once it has sufficiently contacted and/or filled the voids.
>
> Once the biocompatible material is solidified and/or cross-linked in the voids of the e-PTFE substrate, it serves as a solid natural binding surface which tends to promote further endothelial cell attachment and tissue ingrowth which is so critical to proper prosthesis acceptance and healing. As previously noted, prior to the present inventions, no existing method has resulted in good endothelial cell attachment, due to the inert chemical nature of the PTFE surface which allows the layers of endothelial cells to easily peel off. The present invention is an attempt to overcome such deficiencies. As importantly, the structure of the present invention assists in the denuclearization of the e-PTFE structure. Also, a reduction in suture hole bleeding is obtained.

'114 patent, column 2, line 44 through column 3, line 14.

Discussion

In reviewing the record we have uncovered a reference, Kaehler, which is significantly more relevant in determining the patentability of all of the claims pending in this reissue application than the references relied upon by the examiner and renders moot a number of appellants' arguments with regard to the examiner's references. Rather than spend the resources of the Board to determine in the context of a final decision the propriety of the examiner's prior art rejections, we find it more appropriate

to not reach the examiner's prior art rejections in view of the new grounds of rejection set forth below.

We also find it appropriate to not reach the examiner's rejection under 35 U.S.C. § 251 on reissue recapture grounds for two reasons. First, in view of the new grounds of rejection set forth below prosecution may or may not be resumed. If prosecution is continued in this reissue application, in all likelihood, the pending claims will be amended, rendering the present reissue recapture rejection against claims 13-18 moot. Second, the manner in which the reissue recapture doctrine is to be applied within the USPTO is in a state of flux. See Ex parte Eggert, Appeal No. 2001-0790, (Bd. Pat. App. & Int. 2003)(copy available at:

http://www.uspto.gov/web/offices/dcom/bpai/prec/RC010790.pdf)

New Grounds of Rejection under 37 CFR § 1.196(b)

1. Claim 13.

Claim 13 is rejected under 35 U.S.C. § 102(b) as anticipated by Kaehler.

Kaehler describes the implantable prosthesis required by claim 13 on appeal in that Kaehler describes a vascular graft (implantable prosthesis) which comprises a body of PTFE having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and fibrils. The vascular grafts used in Kaehler are reinforced PTFE grafts, Kaehler, pages 536, left-hand column, "Graft material") which are described in the '114 patent as being e-PTFE. '114 patent, column 1, lines 56-63. That the vascular grafts used in Kaehler which comprise e-PTFE contain the claimed node and fibril structure is seen from a complete reading of Kaehler. See, e.g., the

paragraph bridging the columns of page 537 ("In a few areas the nodular structure of the PTFE graft could be recognized . . .. Both surfaces were characterized by alternating areas of an extremely fine meshwork of thin fibrils . . .. shallow folds parallel to the nodes of the graft material.").

Claim 13 requires that the implantable prosthesis comprise a body of e-PTFE that contains a biodegradable composition of natural origin within its pores. The vascular grafts of Kaehler meet this claim limitation as they are coated with a variety of biodegradable products of natural origin which are contained within the pores of the graft. For example, Kaehler describes coating the vascular graft of that reference with a mixture of collagen types I and III as follows:

> **Collagen types I and III**. A commercially available mixture of type I collagen (95%) and type III collagen (5%) was used (vitrogen 100; Collagen Corporation, Palo Alto, Calif.). After adding 12.5% 10x concentrated medium 199 (Flow Laboratories, McLean, Va.) and adjusting to pH 7.2 with 0.1N NaOH, the collagen solution was forced through the graft interstices. After the procedure was repeated three times excess collagen was removed from the graft lumen with a size 3 Fogarty catheter. After 60 minutes of incubation at 37° C the whole procedure was repeated twice. On the third occasion it was almost impossible to force the solution through the graft. Subsequently the graft was air dried for 20 hours at room temperature.

Kaehler, page 536, second column, first paragraph.

As seen, the collagen mixture solidified or precipitated and substantially filled the pores of the expanded polytetrafluoroethylene graft. This passage of Kaehler also teaches that the solidification or precipitation of collagen from its solution depends upon pH and temperature considerations. That the solidified or precipitated collagen substantially filled the pores of the vascular graft is seen in that Kaehler reports that it

was "almost impossible to force the solution through the graft" at the end of the third procedure.

Finally, claim 13 requires that the biodegradable composition which substantially fills the pores of the prosthesis form an insoluble site for cellular attachment. Kaehler also describes this aspect of the claimed invention in that the purpose of Kaehler is to provide a coated e-PTFE vascular graft to enhance the adherence and attachment of seeded human endothelial cells through the graft. See, e.g., the abstract of Kaehler.

Since Kaehler was published more than one year prior to the filing date of the '114 patent and describes the implantable prosthesis required by claim 13 on appeal, Kaehler constitutes a statutory bar under 35 U.S.C. § 102(b).

2. Claims 14-16.

Claims 14-16 are rejected under 35 U.S.C. § 102(b) as anticipated by Kaehler

Claim 14 requires, inter alia, that the biodegradable composition of claim 13 be an extracellular matrix protein which can be collagen (claim 16) or a mixture of collagen I and collagen III (claim 15). As explained above, the biodegradable composition used to coat the expanded polytetrafluoroethylene graft of Kaehler may be a mixture of collagen I and collagen III. Thus, Kaehler anticipates claims 14 through 16.

3. Claims 17 and 18.

Claims 17 and 18 are rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Alonso, and Tran.

Claim 17 requires that the biodegradable composition of claim 14 include a buffered phosphate with claim 18 requiring that the buffered phosphate be maintained at a pH of about 7.4.

Alonso is also concerned with vascular grafts coated with collagen. The vascular grafts of Alonso may be formed from any type of biocompatible mesh. Column 3, lines 7-21. E-PTFE is not explicitly taught by Alonso as being useful in that invention. Be that as it may, Alonso is relevant in determining the patentability of the invention claimed in this reissue application since it discusses the preparation of collagen which is used to coat vascular grafts.

Alonso describes the preparation of a collagen paste which is subsequently diluted in buffer solution to adjust the pH factor to 7.4 in order to form soluble collagen. Alonso, column 3, lines 31-41. The soluble collagen becomes a gel by incubation at 37° C. Alonso, column 3, lines 42-44.

Tran is relevant to the invention claimed in this reissue application because it is also concerned with collagen coated vascular grafts. Vascular grafts are prepared by Tran by coating a PTFE graft with collagen followed by treatment with glutaraldehyde to cross-link the collagen. The cross-linked grafts are then washed in phosphate buffered saline (PBS), stated to be at pH 7.00. Tran, page 375. Thus, Tran provides evidence the PBS is a buffer compatible with collagen.

It would have been obvious to one of ordinary skill in the art to adjust the pH of the collagen types I and III used to coat the e-PTFE vascular graft in Kaehler with PBS maintained at a pH of about 7.4. The reason, suggestion or motivation to do so is

provided by the teachings of Alonso that the collagen solutions such as those used in Kaehler are typically adjusted to a pH of 7.4 using a buffer solution. The use of PBS as a specific buffer to maintain the pH at this level would have been obvious in view of the teachings of Tran that PBS is a buffer typically used with collagen.

4. Claim 1.

Claim 1 is rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Hoffman '977, and Alonso.

Claim 1 is directed to an implantable member for use in repair or replacement with a body which comprises an e-PTFE substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils. As set forth above, Kaehler describes an implantable member which comprises e-PTFE having the required wall structure of nodes and fibrils. Claim 1 also requires that the pores of the implantable member be filled with a fluid which solidifies and is crosslinked to form a solid precipitate of an insoluble biocompatible, biodegradable material of natural origin. As set forth above, the vascular graft of Kaehler also has its pores filled with a fluid which is solidified to form a solid precipitate of an insoluble biocompatible, biodegradable material of natural origin, e.g., a mixture of collagen I and III. Claim 1 also requires that the biocompatible, biodegradable material of natural origin be "insoluble with a pH of about 7.4." Kaehler does not explicitly teach this aspect of claim 1 on appeal. Nor does Kaehler teach that the collagen is crosslinked.

Hoffman '977 and Alonso are relied upon as evidence showing that at the time of the present invention workers of ordinary skill in this field were well aware of collagen

coated synthetic implantable members where the collagen has been crosslinked. Hoffman '977, Example 2 ("Following the fourth application, the collagen was cross-linked by exposure to formaldehyde vapor for 5 minutes."); Alonso, column 4, lines 39-41 ("aqueous glutaraldehyde solution of approximately 7.4 pH is used to cross-link the collagen fibers with one another."). By crosslinking the collagen the strength and blood tightness of the vascular graft are increased. As explained by Alonso:

> Preferably, the corrugated vascular grafts are treated with glutaraldehyde solution in a longitudinally extended position. Still more preferably, the treatment with glutaraldehyde includes placing the glutaraldehyde solution inside the graft under physiological pressure. These features of the process of the present invention are particularly advantageous because they result in vascular grafts which have very good properties of imperviousness. If the vascular grafts were not treated with glutaraldehyde in longitudinally extended position, or under pressure, then, in some instances, the collagen might separate from the fabric during the surgery of implantation or under the patient's natural blood pressure, resulting in disastrous graft failure.
>
> As is known, treatment with glutaraldehyde links the collagen fibers to one another, because it causes covalent chemical bond bridges to form between several protein chains of the fibers. The vascular grafts of the invention are usually stored and transported in glutaraldehyde or saline solution.

Alonso, column 4, lines 42-61.

It would have been obvious to one of ordinary skill in the art to crosslink the collagen impregnated e-PTFE vascular graft of Kaehler using formaldehyde or glutaraldehyde. The reason, suggestion, or motivation to do so is provided by teachings such as those of Alonso that crosslinking collagen coated vascular grafts results in a stronger, more blood tight product. As seen from Alonso, collagen becomes

insoluble at a pH of about 7.4 when it is heated to 37° C. Alonso, column 3, lines 31-46.

5. Claims 2-4.

Claims 2-4 are rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Hoffman '977, and Alonso.

These claims limit the e-PTFE substrate of claim 1 on appeal to an implantable tubular prosthesis (claim 2); an implantable surgical patch (claim 3); and an implantable mesh (claim 4). Clearly the vascular graft of Kaehler is a tubular prosthesis as required by claim 2. As to the requirement of claim 3 that the substrate comprise an implantable "surgical patch," we note that a vascular graft by nature is a "surgical patch." Furthermore, since the e-PTFE vascular graft of Kaehler has a node and fibril structure resulting in the material being porous, it can be considered an implantable "mesh" as required by claim 4 on appeal.

Thus, for the reasons set forth above, the subject matter of each of claims 2, 3, and 4 as a whole would have been obvious to one of ordinary skill in the art from a consideration of Kaehler, Alonso, and Hoffman '977.

6. Claim 5.

Claim 5 is rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Hoffman '977, and Alonso.

Claim 5 further limits claim 1 in requiring the insoluble biocompatible biodegradable material to substantially fill the pores of the e-PTFE substrate to render the substrate blood-tight. As explained above, the mixture of collagen I and III used to impregnate the e-PTFE vascular graft of Kaehler substantially fills the pores of that

device. Once the collagen is cross-linked as suggested by Alonso and Hoffman '977, the resulting product would be "blood-tight" as required by claim 5 on appeal.

For the reason set forth above, the subject matter of claim 5 as a whole would have been obvious to one of ordinary skill in the art from the consideration Kaehler, Alonso, and Hoffman '977.

7. Claims 6-8.

Claims 6-8 are rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Hoffman '977, and Alonso.

Claim 6 requires that the biocompatible, biodegradable material of claim 1 include extracellular matrix proteins with claim 7 further requiring that the extracellular matrix protein be selected from a Markush group which includes mixtures of collagen I and collagen III. As explained above, the e-PTFE vascular graft of Kaehler is impregnated with a mixture of collagen I and III. Furthermore, as set forth above, Alonso and Hoffman '977 provide ample reason, suggestion, and motivation to crosslink the collagen impregnated vascular graft of Kaehler to strengthen that product and to make it more blood-tight.

Thus, for the reason set forth above, the subject matter of each of claims 6, 7, and 8 in its entirety would have been obvious to one of ordinary skill in the art from a consideration of Kaehler, Alonso, and Hoffman '977.

8. Claims 9 and 10.

Claims 9 and 10 are rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Hoffman '977, and Alonso.

Claim 9 requires that the biocompatible biodegradable material of claim 1 further include a pharmacological agent with claim 10 defining that the pharmacologically active agent may be an antimicrobial.

Hoffman '977 provides:

> In accordance with the invention, the collagen in at least the last two application to a porous substrate are chemically modified to incorporate a drug or an antithrombic agent, such as heprin, in order to prevent infection and to inhibit clotting along the inner surface of the prosthesis. As noted, the collagen may be complexed with a variety of drugs, such as antibacterial agents, antimicrobial agents or antifungal agents in order to prevent graft infection. Typical antibacterial agents which may be utilized include oxacillin, gentamicin, tetracycline, cephalosporin and the like which may be complexed with the collagen fibrils prior to application to the graft substrate.

Hoffman '977, paragraph bridging columns 5 and 6.

It would have been obvious to one of ordinary skill in the art to include a pharmacologically active agent such as an antimicrobial in the expanded polytetrafluoroethylene vascular graft of Kaehler. The reason, suggestion, or motivation to do is provided by the above discussed disclosure of Hoffman '977.

9. Claims 11 and 12.

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a). As evidence of obviousness, we rely upon Kaehler, Hoffman '977, Alonso, and Tran.

Claim 11 requires that the polytetrafluoroethylene substrate of claim 1 be modified to enhance its hydrophilic character with claim 12 requiring that that be accomplished by subjecting the substrate to glow discharge plasma deposition.

Tran also describes polytetrafluoroethylene grafts which are coated with collagen. Prior to applying the collagen to the PTFE substrate, the substrate is provided with a blue discharge plasma deposition. Tran, page 374 ("The plasma depositions were formed using . . . an electrical chemical induction coupled glow discharge system.") As a result of the glow discharge plasma deposition, the PTFE is rendered more hydrophilic and thus more receptive to the subsequent collagen coating. See, e.g., Tran, page 379 including Table III.

It would have been obvious to one of ordinary skill in the art to pretreat the e-PTFE vascular graft substrate of Kaehler by subjecting it to a glow discharge plasma deposition process as suggested by Tran. By doing so, the hydrophobic PTFE surface of Kaehler will be rendered more hydrophilic and thus more receptive to the subsequent impregnation by collagen. The reason, suggestion or motivation to modify Kaehler is provided by the above identified teachings of Tran.

10. Claim definiteness.

Claims 1 through 12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The manner in which claim 1 was amended in the '790 application by way of the Examiner's Amendment renders claim 1 at the least ambiguous. As set forth in In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989):

> [D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. . . . An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in

this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

Prior to its amendment in the '790 application, claim 1 set forth an implantable member comprising an e-PTFE substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils. The claim went on to require that "said pores containing a solid insoluble biocompatible, biodegradable material of natural origin." The claim was amended to require that the pores are "filled with a fluid which solidifies and is crosslinked to form a solid precipitate . . .." The ambiguity exists in that the claim positively states that the pores are filled with a fluid. However, the claim then goes on to state that the fluid "solidifies and is crosslinked to form a solid precipitate . . .." It is not clear whether claim 1 is directed to an intermediate product which would comprise the e-PTFE substrate having its pores filled with a fluid which at some unspecified future point in time will be solidified and crosslinked or whether claim 1 is intended to be directed to a final product where the e-PTFE substrate has its pores filled with a fluid which has been solidified and crosslinked.

If prosecution is resumed in this reissue application, patentees should state on the record their intention as to which product(s) claim 1 is intended to encompass, i.e., an intermediate product, a final product, or both, an intermediate and final product.

The requirement of claim 1 that the material is "insoluble at a pH of about 7.4" creates another ambiguity. The only mention of this requirement in the specification of the '114 patent is found at column 6, lines 11-15 where a collagen treated prosthesis is

"treated with a chemical solution, such as buffered phosphate at a pH of about 7.4 to insolubilize the biocompatible material in place." It appears that the pH of about 7.4 limitation is specific to collagen and may not apply to the other biocompatible, biodegradable materials included within the scope of claim 1 on appeal. Thus, it is not clear whether claim 1 is limited to the use of collagen as the biocompatible, biodegradable material of natural origin or whether any of the other specific materials described and claimed in this patent also possess the property of being insoluble at a pH of about 7.4. To the extent that "extracellular matrix proteins" of claim 6 and the specified proteins of claim 7 do not meet this pH requirement, claims 6 and 7 may be improper dependent claims.

Furthermore, to the extent patentees believe this pH requirement is specific to collagen, they need to take a step back and consider this issue anew. Alonso indicates that collagen at a pH of 7.4 is soluble, not insoluble, unless the solution is heated to 37° C, at which point the soluble collagen gels or solidifies. See, Alonso, column 3, lines 31-44. The information provided by Alonso is confirmed by the information provided by a company named Cohesion Tech. which markets vitrogen collagen gels. It is of interest that Kaehler uses as its mixture of collagen types I and III a commercially available mixture sold under the trade name vitrogen 100. Kaehler, page 536. As seen from the attached printout from the Cohension Tech. website[2], the pH of the collagen

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[2] http://www.cohesiontech.com/products/provitrogentop.html Web site accessed April 7, 2003

solution is adjusted to about 7.4 prior to gelation. Gelation is initiated or promoted by incubating the collagen solution at a pH of 7.4 at a temperature of 37° C.

If prosecution is resumed in this reissue application, the examiner and patentees should review the requirement of claim 1 that the material be insoluble at a pH of about 7.4 and determine whether that limitation in effect limits claim 1 to the use of collagen as the biocompatible, biodegradable material and whether the requirement makes any sense in the absence of a concomitant temperature requirement.

Claim 5 is indefinite in that it appears to be in conflict with claim 1. Claim 5 requires that the insoluble biocompatible, biodegradable material substantially fill the pores of the expanded polytetrafluoroethylene substrate. However, claim 1 requires that the pores are filled with the biocompatible, biodegradable material. It is not clear what appellants intend by maintaining claim 5 in the presence of the requirement of claim 1 that the pores are "filled" with the material. Clarification is needed.

Claim 8 appears to be redundant to claim 1 in that claim 1 was amended in the '790 application to include the "crosslinked" language. Again, clarification is needed.

Time Period for Response

This decision contains new grounds of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with

respect to the new grounds of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

37 CFR § 1.196(b)

William F. Smith
Administrative Patent Judge

Jeffrey V. Nase
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

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Hoffman & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791

dem